

Union Calendar No. 521

110TH CONGRESS
2D SESSION

H. R. 6433

[Report No. 110–805]

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to generic new animal drugs.

IN THE HOUSE OF REPRESENTATIVES

JULY 8, 2008

Mr. PALLONE (for himself, Mr. DINGELL, Mr. BARTON of Texas, Mr. DEAL of Georgia, and Mr. TOWNS) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY 30, 2008

Additional sponsor: Ms. DEGETTE

JULY 30, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on July 8, 2008]

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to generic new animal drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCES.**

2 (a) *SHORT TITLE.*—*This Act may be cited as the*
3 *“Animal Generic Drug User Fee Act of 2008”.*

4 (b) *REFERENCES IN ACT.*—*Except as otherwise speci-*
5 *fied, amendments made by this Act to a section or other*
6 *provision of law are amendments to such section or other*
7 *provision of the Federal Food, Drug, and Cosmetic Act (21*
8 *U.S.C. 301 et seq.).*

9 **SEC. 2. FINDINGS.**

10 *Congress finds as follows:*

11 (1) *Prompt approval of abbreviated applications*
12 *for safe and effective generic new animal drugs will*
13 *reduce animal healthcare costs and promote the well-*
14 *being of animal health and the public health.*

15 (2) *Animal health and the public health will be*
16 *served by making additional funds available for the*
17 *purpose of augmenting the resources of the Food and*
18 *Drug Administration that are devoted to the process*
19 *for the review of abbreviated applications for the ap-*
20 *proval of generic new animal drugs.*

21 (3) *The fees authorized by this Act will be dedi-*
22 *cated toward expediting the generic new animal drug*
23 *development process and the review of abbreviated ap-*
24 *plications for generic new animal drugs, supple-*
25 *mental abbreviated applications for generic new ani-*
26 *mal drugs, and investigational submissions for ge-*

1 *neric new animal drugs as set forth in the goals iden-*
 2 *tified in the letters from the Secretary of Health and*
 3 *Human Services to the Chairman of the Committee*
 4 *on Energy and Commerce of the House of Representa-*
 5 *tives and the Chairman of the Committee on Health,*
 6 *Education, Labor, and Pensions of the Senate as set*
 7 *forth in the Congressional Record.*

8 **SEC. 3. FEES RELATING TO ABBREVIATED APPLICATIONS**
 9 **FOR GENERIC NEW ANIMAL DRUGS.**

10 (a) *REDESIGNATION*.—Chapter VII (21 U.S.C. 371 *et*
 11 *seq.*) is amended by redesignating sections 741, 742, and
 12 746 as sections 745, 746, and 749, respectively.

13 (b) *AUTHORITY TO ASSESS AND USE GENERIC NEW*
 14 *ANIMAL DRUG FEES*.—Subchapter C of chapter VII of the
 15 *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 379f *et*
 16 *seq.*) is amended by adding at the end the following:

17 **“PART 5—FEES RELATING TO GENERIC NEW**
 18 **ANIMAL DRUGS**

19 **“SEC. 741. AUTHORITY TO ASSESS AND USE GENERIC NEW**
 20 **ANIMAL DRUG FEES.**

21 “(a) *TYPES OF FEES*.—Beginning with respect to fis-
 22 *cal year 2009, the Secretary shall assess and collect fees in*
 23 *accordance with this section as follows:*

24 “(1) *ABBREVIATED APPLICATION FEE*.—

1 “(A) *IN GENERAL.*—Each person that sub-
2 mits, on or after July 1, 2008, an abbreviated
3 application for a generic new animal drug shall
4 be subject to a fee as established in subsection (b)
5 for such an application.

6 “(B) *PAYMENT.*—The fee required by sub-
7 paragraph (A) shall be due upon submission of
8 the abbreviated application.

9 “(C) *EXCEPTION FOR PREVIOUSLY FILED*
10 *APPLICATION.*—If an abbreviated application
11 was submitted by a person that paid the fee for
12 such application, was accepted for filing, and
13 was not approved or was withdrawn (without a
14 waiver or refund), the submission of an abbre-
15 viated application for the same product by the
16 same person (or the person’s licensee, assignee, or
17 successor) shall not be subject to a fee under sub-
18 paragraph (A).

19 “(D) *REFUND OF FEE IF APPLICATION RE-*
20 *FUSED FOR FILING.*—The Secretary shall refund
21 75 percent of the fee paid under subparagraph
22 (B) for any abbreviated application which is re-
23 fused for filing.

24 “(E) *REFUND OF FEE IF APPLICATION*
25 *WITHDRAWN.*—If an abbreviated application is

1 *withdrawn after the application was filed, the*
2 *Secretary may refund the fee or portion of the fee*
3 *paid under subparagraph (B) if no substantial*
4 *work was performed on the application after the*
5 *application was filed. The Secretary shall have*
6 *the sole discretion to refund the fee under this*
7 *subparagraph. A determination by the Secretary*
8 *concerning a refund under this subparagraph*
9 *shall not be reviewable.*

10 *“(2) GENERIC NEW ANIMAL DRUG PRODUCT*
11 *FEE.—Each person—*

12 *“(A) who is named as the applicant in an*
13 *abbreviated application or supplemental abbrev-*
14 *viated application for a generic new animal*
15 *drug product which has been submitted for list-*
16 *ing under section 510, and*

17 *“(B) who, after September 1, 2008, had*
18 *pending before the Secretary an abbreviated ap-*
19 *plication or supplemental abbreviated applica-*
20 *tion,*

21 *shall pay for each such generic new animal drug*
22 *product the annual fee established in subsection (b).*
23 *Such fee shall be payable for the fiscal year in which*
24 *the generic new animal drug product is first sub-*
25 *mitted for listing under section 510, or is submitted*

1 *for relisting under section 510 if the generic new ani-*
 2 *mal drug product has been withdrawn from listing*
 3 *and relisted. After such fee is paid for that fiscal*
 4 *year, such fee shall be payable on or before January*
 5 *31 of each year. Such fee shall be paid only once for*
 6 *each generic new animal drug product for a fiscal*
 7 *year in which the fee is payable.*

8 “(3) *GENERIC NEW ANIMAL DRUG SPONSOR*
 9 *FEE.*—

10 “(A) *IN GENERAL.*—Each person—

11 “(i) *who meets the definition of a ge-*
 12 *neric new animal drug sponsor within a*
 13 *fiscal year, and*

14 “(ii) *who, after September 1, 2008, had*
 15 *pending before the Secretary an abbreviated*
 16 *application, a supplemental abbreviated ap-*
 17 *plication, or an investigational submission,*
 18 *shall be assessed an annual fee established under*
 19 *subsection (b). The fee shall be paid on or before*
 20 *January 31 of each year.*

21 “(B) *AMOUNT OF FEE.*—Each generic new
 22 *animal drug sponsor shall pay only 1 such fee*
 23 *each fiscal year, as follows:*

24 “(i) *100 percent of the amount of the*
 25 *generic new animal drug sponsor fee pub-*

lished for that fiscal year under subsection (c)(3) for an applicant with more than 6 approved abbreviated applications.

“(ii) 75 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with more than 1 and fewer than 7 approved abbreviated applications.

“(iii) 50 percent of the amount of the generic new animal drug sponsor fee published for that fiscal year under subsection (c)(3) for an applicant with 1 or fewer approved abbreviated applications.

“(b) *FEE AMOUNTS.*—Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

“(1) *TOTAL FEE REVENUES FOR APPLICATION FEES.*—The total fee revenues to be collected in abbreviated application fees under subsection (a)(1) shall be \$1,449,000 for fiscal year 2009, \$1,532,000 for fiscal year 2010, \$1,619,000 for fiscal year 2011, \$1,712,000 for fiscal year 2012, and \$1,809,000 for fiscal year 2013.

1 “(2) *TOTAL FEE REVENUES FOR PRODUCT*
2 *FEES.*—*The total fee revenues to be collected in ge-*
3 *neric new animal drug product fees under subsection*
4 *(a)(2) shall be \$1,691,000 for fiscal year 2009,*
5 *\$1,787,000 for fiscal year 2010, \$1,889,000 for fiscal*
6 *year 2011, \$1,997,000 for fiscal year 2012, and*
7 *\$2,111,000 for fiscal year 2013.*

8 “(3) *TOTAL FEE REVENUES FOR SPONSOR*
9 *FEES.*—*The total fee revenues to be collected in ge-*
10 *neric new animal drug sponsor fees under subsection*
11 *(a)(3) shall be \$1,691,000 for fiscal year 2009,*
12 *\$1,787,000 for fiscal year 2010, \$1,889,000 for fiscal*
13 *year 2011, \$1,997,000 for fiscal year 2012, and*
14 *\$2,111,000 for fiscal year 2013.*

15 “(c) *ADJUSTMENTS.*—

16 “(1) *WORKLOAD ADJUSTMENT.*—*The fee revenues*
17 *shall be adjusted each fiscal year after fiscal year*
18 *2009 to reflect changes in review workload. With re-*
19 *spect to such adjustment:*

20 “(A) *This adjustment shall be determined*
21 *by the Secretary based on a weighted average of*
22 *the change in the total number of abbreviated*
23 *applications for generic new animal drugs, man-*
24 *ufacturing supplemental abbreviated applica-*
25 *tions for generic new animal drugs, investiga-*

1 *tional generic new animal drug study submis-*
2 *sions, and investigational generic new animal*
3 *drug protocol submissions submitted to the Sec-*
4 *retary. The Secretary shall publish in the Fed-*
5 *eral Register the fees resulting from this adjust-*
6 *ment and the supporting methodologies.*

7 *“(B) Under no circumstances shall this*
8 *workload adjustment result in fee revenues for a*
9 *fiscal year that are less than the fee revenues for*
10 *that fiscal year established in subsection (b).*

11 *“(2) FINAL YEAR ADJUSTMENT.—For fiscal year*
12 *2013, the Secretary may further increase the fees to*
13 *provide for up to 3 months of operating reserves of*
14 *carryover user fees for the process for the review of ab-*
15 *breivated applications for generic new animal drugs*
16 *for the first 3 months of fiscal year 2014. If the Food*
17 *and Drug Administration has carryover balances for*
18 *the process for the review of abbreviated applications*
19 *for generic new animal drugs in excess of 3 months*
20 *of such operating reserves, then this adjustment shall*
21 *not be made. If this adjustment is necessary, then the*
22 *rationale for the amount of the increase shall be con-*
23 *tained in the annual notice setting fees for fiscal year*
24 *2013.*

1 “(3) *ANNUAL FEE SETTING.*—*The Secretary shall*
2 *establish, 60 days before the start of each fiscal year*
3 *beginning after September 30, 2008, for that fiscal*
4 *year, abbreviated application fees, generic new ani-*
5 *mal drug sponsor fees, and generic new animal drug*
6 *product fees based on the revenue amounts established*
7 *under subsection (b) and the adjustments provided*
8 *under this subsection.*

9 “(4) *LIMIT.*—*The total amount of fees charged,*
10 *as adjusted under this subsection, for a fiscal year*
11 *may not exceed the total costs for such fiscal year for*
12 *the resources allocated for the process for the review*
13 *of abbreviated applications for generic new animal*
14 *drugs.*

15 “(d) *FEE WAIVER OR REDUCTION.*—*The Secretary*
16 *shall grant a waiver from or a reduction of 1 or more fees*
17 *assessed under subsection (a) where the Secretary finds that*
18 *the generic new animal drug is intended solely to provide*
19 *for a minor use or minor species indication.*

20 “(e) *EFFECT OF FAILURE TO PAY FEES.*—*An abbre-*
21 *viated application for a generic new animal drug submitted*
22 *by a person subject to fees under subsection (a) shall be con-*
23 *sidered incomplete and shall not be accepted for filing by*
24 *the Secretary until all fees owed by such person have been*
25 *paid. An investigational submission for a generic new ani-*

1 *mal drug that is submitted by a person subject to fees under*
2 *subsection (a) shall be considered incomplete and shall not*
3 *be accepted for review by the Secretary until all fees owed*
4 *by such person have been paid. The Secretary may dis-*
5 *continue review of any abbreviated application for a ge-*
6 *neric new animal drug, supplemental abbreviated applica-*
7 *tion for a generic new animal drug, or investigational sub-*
8 *mission for a generic new animal drug from a person if*
9 *such person has not submitted for payment all fees owed*
10 *under this section by 30 days after the date upon which*
11 *they are due.*

12 “(f) *ASSESSMENT OF FEES.*—

13 “(1) *LIMITATION.*—*Fees may not be assessed*
14 *under subsection (a) for a fiscal year beginning after*
15 *fiscal year 2008 unless appropriations for salaries*
16 *and expenses of the Food and Drug Administration*
17 *for such fiscal year (excluding the amount of fees ap-*
18 *propriated for such fiscal year) are equal to or greater*
19 *than the amount of appropriations for the salaries*
20 *and expenses of the Food and Drug Administration*
21 *for the fiscal year 2003 (excluding the amount of fees*
22 *appropriated for such fiscal year) multiplied by the*
23 *adjustment factor applicable to the fiscal year in-*
24 *volved.*

1 “(2) *AUTHORITY.*—*If the Secretary does not as-*
2 *sess fees under subsection (a) during any portion of*
3 *a fiscal year because of paragraph (1) and if at a*
4 *later date in such fiscal year the Secretary may assess*
5 *such fees, the Secretary may assess and collect such*
6 *fees, without any modification in the rate, for abbrev-*
7 *viated applications, generic new animal drug spon-*
8 *sors, and generic new animal drug products at any*
9 *time in such fiscal year notwithstanding the provi-*
10 *sions of subsection (a) relating to the date fees are to*
11 *be paid.*

12 “(g) *CREDITING AND AVAILABILITY OF FEES.*—

13 “(1) *IN GENERAL.*—*Fees authorized under sub-*
14 *section (a) shall be collected and available for obliga-*
15 *tion only to the extent and in the amount provided*
16 *in advance in appropriations Acts. Such fees are au-*
17 *thorized to be appropriated to remain available until*
18 *expended. Such sums as may be necessary may be*
19 *transferred from the Food and Drug Administration*
20 *salaries and expenses appropriation account without*
21 *fiscal year limitation to such appropriation account*
22 *for salary and expenses with such fiscal year limita-*
23 *tion. The sums transferred shall be available solely for*
24 *the process for the review of abbreviated applications*
25 *for generic new animal drugs.*

1 “(2) *COLLECTIONS AND APPROPRIATION ACTS.*—

2 “(A) *IN GENERAL.*—*The fees authorized by*
3 *this section—*

4 “(i) *shall be retained in each fiscal*
5 *year in an amount not to exceed the*
6 *amount specified in appropriation Acts, or*
7 *otherwise made available for obligation for*
8 *such fiscal year; and*

9 “(ii) *shall only be collected and avail-*
10 *able to defray increases in the costs of the*
11 *resources allocated for the process for the re-*
12 *view of abbreviated applications for generic*
13 *new animal drugs (including increases in*
14 *such costs for an additional number of full-*
15 *time equivalent positions in the Department*
16 *of Health and Human Services to be en-*
17 *gaged in such process) over such costs, ex-*
18 *cluding costs paid from fees collected under*
19 *this section, for fiscal year 2008 multiplied*
20 *by the adjustment factor.*

21 “(B) *COMPLIANCE.*—*The Secretary shall be*
22 *considered to have met the requirements of sub-*
23 *paragraph (A)(ii) in any fiscal year if the costs*
24 *funded by appropriations and allocated for the*

1 *process for the review of abbreviated applications*
 2 *for generic new animal drugs—*

3 *“(i) are not more than 3 percent below*
 4 *the level specified in subparagraph (A)(ii);*
 5 *or*

6 *“(ii)(I) are more than 3 percent below*
 7 *the level specified in subparagraph (A)(ii),*
 8 *and fees assessed for the fiscal year fol-*
 9 *lowing the subsequent fiscal year are de-*
 10 *creased by the amount in excess of 3 percent*
 11 *by which such costs fell below the level speci-*
 12 *fied in subparagraph (A)(ii); and*

13 *“(II) such costs are not more than 5*
 14 *percent below the level specified in subpara-*
 15 *graph (A)(ii).*

16 “(3) *AUTHORIZATION OF APPROPRIATIONS.—*
 17 *There are authorized to be appropriated for fees under*
 18 *this section—*

19 *“(A) \$4,831,000 for fiscal year 2009;*

20 *“(B) \$5,106,000 for fiscal year 2010;*

21 *“(C) \$5,397,000 for fiscal year 2011;*

22 *“(D) \$5,706,000 for fiscal year 2012; and*

23 *“(E) \$6,031,000 for fiscal year 2013;*

24 *as adjusted to reflect adjustments in the total fee reve-*
 25 *nues made under this section and changes in the total*

1 *amounts collected by abbreviated application fees, ge-*
2 *neric new animal drug sponsor fees, and generic new*
3 *animal drug product fees.*

4 “(4) *OFFSET.—If the sum of the cumulative*
5 *amount of fees collected under this section for the fis-*
6 *cal years 2009 through 2011 and the amount of fees*
7 *estimated to be collected under this section for fiscal*
8 *year 2012 exceeds the cumulative amount appro-*
9 *priated under paragraph (3) for the fiscal years 2009*
10 *through 2012, the excess amount shall be credited to*
11 *the appropriation account of the Food and Drug Ad-*
12 *ministration as provided in paragraph (1), and shall*
13 *be subtracted from the amount of fees that would oth-*
14 *erwise be authorized to be collected under this section*
15 *pursuant to appropriation Acts for fiscal year 2013.*

16 “(h) *COLLECTION OF UNPAID FEES.—In any case*
17 *where the Secretary does not receive payment of a fee as-*
18 *sessed under subsection (a) within 30 days after it is due,*
19 *such fee shall be treated as a claim of the United States*
20 *Government subject to subchapter II of chapter 37 of title*
21 *31, United States Code.*

22 “(i) *WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS,*
23 *AND REFUNDS.—To qualify for consideration for a waiver*
24 *or reduction under subsection (d), or for a refund of any*
25 *fee collected in accordance with subsection (a), a person*

1 *shall submit to the Secretary a written request for such*
 2 *waiver, reduction, or refund not later than 180 days after*
 3 *such fee is due.*

4 “(j) *CONSTRUCTION.*—*This section may not be con-*
 5 *strued to require that the number of full-time equivalent*
 6 *positions in the Department of Health and Human Serv-*
 7 *ices, for officers, employees, and advisory committees not*
 8 *engaged in the process of the review of abbreviated applica-*
 9 *tions for generic new animal drugs, be reduced to offset the*
 10 *number of officers, employees, and advisory committees so*
 11 *engaged.*

12 “(k) *DEFINITIONS.*—*In this section and section 742:*

13 “(1) *ABBREVIATED APPLICATION FOR A GENERIC*
 14 *NEW ANIMAL DRUG.*—*The terms ‘abbreviated applica-*
 15 *tion for a generic new animal drug’ and ‘abbreviated*
 16 *application’ mean an abbreviated application for the*
 17 *approval of any generic new animal drug submitted*
 18 *under section 512(b)(2). Such term does not include*
 19 *a supplemental abbreviated application for a generic*
 20 *new animal drug.*

21 “(2) *ADJUSTMENT FACTOR.*—*The term ‘adjust-*
 22 *ment factor’ applicable to a fiscal year is the Con-*
 23 *sumer Price Index for all urban consumers (all items;*
 24 *United States city average) for October of the pre-*
 25 *ceding fiscal year divided by—*

1 “(A) for purposes of subsection (f)(1), such
2 Index for October 2002; and

3 “(B) for purposes of subsection (g)(2)(A)(ii),
4 such Index for October 2007.

5 “(3) COSTS OF RESOURCES ALLOCATED FOR THE
6 PROCESS FOR THE REVIEW OF ABBREVIATED APPLI-
7 CATIONS FOR GENERIC NEW ANIMAL DRUGS.—The
8 term ‘costs of resources allocated for the process for the
9 review of abbreviated applications for generic new
10 animal drugs’ means the expenses incurred in connec-
11 tion with the process for the review of abbreviated ap-
12 plications for generic new animal drugs for—

13 “(A) officers and employees of the Food and
14 Drug Administration, contractors of the Food
15 and Drug Administration, advisory committees
16 consulted with respect to the review of specific
17 abbreviated applications, supplemental abbre-
18 viated applications, or investigational submis-
19 sions, and costs related to such officers, employ-
20 ees, committees, and contractors, including costs
21 for travel, education, and recruitment and other
22 personnel activities;

23 “(B) management of information, and the
24 acquisition, maintenance, and repair of com-
25 puter resources;

1 “(C) leasing, maintenance, renovation, and
2 repair of facilities and acquisition, maintenance,
3 and repair of fixtures, furniture, scientific equip-
4 ment, and other necessary materials and sup-
5 plies; and

6 “(D) collecting fees under this section and
7 accounting for resources allocated for the review
8 of abbreviated applications, supplemental abbrevi-
9 ated applications, and investigational submis-
10 sions.

11 “(4) *FINAL DOSAGE FORM*.—The term ‘final dos-
12 age form’ means, with respect to a generic new ani-
13 mal drug product, a finished dosage form which is
14 approved for administration to an animal without
15 substantial further manufacturing. Such term in-
16 cludes generic new animal drug products intended for
17 mixing in animal feeds.

18 “(5) *GENERIC NEW ANIMAL DRUG*.—The term
19 ‘generic new animal drug’ means a new animal drug
20 that is the subject of an abbreviated application.

21 “(6) *GENERIC NEW ANIMAL DRUG PRODUCT*.—
22 The term ‘generic new animal drug product’ means
23 each specific strength or potency of a particular ac-
24 tive ingredient or ingredients in final dosage form
25 marketed by a particular manufacturer or dis-

1 *tributor, which is uniquely identified by the labeler*
2 *code and product code portions of the national drug*
3 *code, and for which an abbreviated application for a*
4 *generic new animal drug or a supplemental abbrevi-*
5 *ated application has been approved.*

6 “(7) *GENERIC NEW ANIMAL DRUG SPONSOR.—*
7 *The term ‘generic new animal drug sponsor’ means*
8 *either an applicant named in an abbreviated applica-*
9 *tion for a generic new animal drug that has not been*
10 *withdrawn by the applicant and for which approval*
11 *has not been withdrawn by the Secretary, or a person*
12 *who has submitted an investigational submission for*
13 *a generic new animal drug that has not been termi-*
14 *nated or otherwise rendered inactive by the Secretary.*

15 “(8) *INVESTIGATIONAL SUBMISSION FOR A GE-*
16 *NERIC NEW ANIMAL DRUG.—The terms ‘investiga-*
17 *tional submission for a generic new animal drug’ and*
18 *‘investigational submission’ mean—*

19 “(A) *the filing of a claim for an investiga-*
20 *tional exemption under section 512(j) for a ge-*
21 *neric new animal drug intended to be the subject*
22 *of an abbreviated application or a supplemental*
23 *abbreviated application; or*

24 “(B) *the submission of information for the*
25 *purpose of enabling the Secretary to evaluate the*

1 *safety or effectiveness of a generic new animal*
2 *drug in the event of the filing of an abbreviated*
3 *application or supplemental abbreviated applica-*
4 *tion for such drug.*

5 “(9) *PERSON.*—*The term ‘person’ includes an af-*
6 *filiate thereof (as such term is defined in section*
7 *735(11)).*

8 “(10) *PROCESS FOR THE REVIEW OF ABBRE-*
9 *VIATED APPLICATIONS FOR GENERIC NEW ANIMAL*
10 *DRUGS.*—*The term ‘process for the review of abbre-*
11 *viated applications for generic new animal drugs’*
12 *means the following activities of the Secretary with*
13 *respect to the review of abbreviated applications, sup-*
14 *plemental abbreviated applications, and investiga-*
15 *tional submissions:*

16 “(A) *The activities necessary for the review*
17 *of abbreviated applications, supplemental abbre-*
18 *viated applications, and investigational submis-*
19 *sions.*

20 “(B) *The issuance of action letters which*
21 *approve abbreviated applications or supple-*
22 *mental abbreviated applications or which set*
23 *forth in detail the specific deficiencies in abbre-*
24 *viated applications, supplemental abbreviated*
25 *applications, or investigational submissions and,*

1 *where appropriate, the actions necessary to place*
2 *such applications, supplemental applications, or*
3 *submissions in condition for approval.*

4 *“(C) The inspection of generic new animal*
5 *drug establishments and other facilities under-*
6 *taken as part of the Secretary’s review of pend-*
7 *ing abbreviated applications, supplemental ab-*
8 *breivated applications, and investigational sub-*
9 *missions.*

10 *“(D) Monitoring of research conducted in*
11 *connection with the review of abbreviated appli-*
12 *cations, supplemental abbreviated applications,*
13 *and investigational submissions.*

14 *“(E) The development of regulations and*
15 *policy related to the review of abbreviated appli-*
16 *cations, supplemental abbreviated applications,*
17 *and investigational submissions.*

18 *“(F) Development of standards for products*
19 *subject to review.*

20 *“(G) Meetings between the agency and the*
21 *generic new animal drug sponsor.*

22 *“(H) Review of advertising and labeling*
23 *prior to approval of an abbreviated application*
24 *or supplemental abbreviated application, but not*
25 *after such application has been approved.*

1 “(11) *SUPPLEMENTAL ABBREVIATED APPLICA-*
 2 *TION FOR GENERIC NEW ANIMAL DRUG.*—*The terms*
 3 *‘supplemental abbreviated application for a generic*
 4 *new animal drug’ and ‘supplemental abbreviated ap-*
 5 *plication’ mean a request to the Secretary to approve*
 6 *a change in an approved abbreviated application.’.*”.

7 **SEC. 4. ACCOUNTABILITY AND REPORTS.**

8 *Part 5 of subchapter C of chapter VII of the Federal*
 9 *Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.), as*
 10 *added by section 3, is amended by inserting after section*
 11 *741 the following:*

12 **“SEC. 742. REAUTHORIZATION; REPORTING REQUIRE-**
 13 **MENTS.**

14 “(a) *PERFORMANCE REPORTS.*—*Beginning with fiscal*
 15 *year 2009, not later than 60 days after the end of each fiscal*
 16 *year during which fees are collected under this part, the*
 17 *Secretary shall prepare and submit to the Committee on*
 18 *Health, Education, Labor, and Pensions of the Senate, and*
 19 *the Committee on Energy and Commerce of the House of*
 20 *Representatives a report concerning the progress of the Food*
 21 *and Drug Administration in achieving the goals identified*
 22 *in the letters described in section 2(3) of the Animal Generic*
 23 *Drug User Fee Act of 2008 toward expediting the generic*
 24 *new animal drug development process and the review of ab-*
 25 *breivated applications for generic new animal drugs, sup-*

1 *plemental abbreviated applications for generic new animal*
2 *drugs, and investigational submissions for generic new ani-*
3 *mal drugs during such fiscal year.*

4 “(b) *FISCAL REPORT.*—*Beginning with fiscal year*
5 *2009, not later than 120 days after the end of each fiscal*
6 *year during which fees are collected under this part, the*
7 *Secretary shall prepare and submit to Committee on*
8 *Health, Education, Labor, and Pensions of the Senate and*
9 *the Committee on Energy and Commerce of the House of*
10 *Representatives a report on the implementation of the au-*
11 *thority for such fees during such fiscal year and the use,*
12 *by the Food and Drug Administration, of the fees collected*
13 *during such fiscal year for which the report is made.*

14 “(c) *PUBLIC AVAILABILITY.*—*The Secretary shall make*
15 *the reports required under subsections (a) and (b) available*
16 *to the public on the Internet Web site of the Food and Drug*
17 *Administration.*

18 “(d) *REAUTHORIZATION.*—

19 “(1) *CONSULTATION.*—*In developing rec-*
20 *ommendations to present to Congress with respect to*
21 *the goals, and plans for meeting the goals, for the*
22 *process for the review of abbreviated applications for*
23 *generic new animal drugs for the first 5 fiscal years*
24 *after fiscal year 2013, and for the reauthorization of*

1 *this part for such fiscal years, the Secretary shall con-*
2 *sult with—*

3 “(A) *the Committee on Energy and Com-*
4 *merce of the House of Representatives;*

5 “(B) *the Committee on Health, Education,*
6 *Labor, and Pensions of the Senate;*

7 “(C) *scientific and academic experts;*

8 “(D) *veterinary professionals;*

9 “(E) *representatives of patient and con-*
10 *sumer advocacy groups; and*

11 “(F) *the regulated industry.*

12 “(2) *PRIOR PUBLIC INPUT.—Prior to beginning*
13 *negotiations with the regulated industry on the reau-*
14 *thorization of this part, the Secretary shall—*

15 “(A) *publish a notice in the Federal Reg-*
16 *ister requesting public input on the reauthoriza-*
17 *tion;*

18 “(B) *hold a public meeting at which the*
19 *public may present its views on the reauthoriza-*
20 *tion, including specific suggestions for changes to*
21 *the goals referred to in subsection (a);*

22 “(C) *provide a period of 30 days after the*
23 *public meeting to obtain written comments from*
24 *the public suggesting changes to this part; and*

1 “(D) publish the comments on the Food and
2 Drug Administration’s Internet Web site.

3 “(3) *PERIODIC CONSULTATION*.—Not less fre-
4 quently than once every 4 months during negotiations
5 with the regulated industry, the Secretary shall hold
6 discussions with representatives of veterinary, patient,
7 and consumer advocacy groups to continue discus-
8 sions of their views on the reauthorization and their
9 suggestions for changes to this part as expressed
10 under paragraph (2).

11 “(4) *PUBLIC REVIEW OF RECOMMENDATIONS*.—
12 After negotiations with the regulated industry, the
13 Secretary shall—

14 “(A) present the recommendations developed
15 under paragraph (1) to the congressional com-
16 mittees specified in such paragraph;

17 “(B) publish such recommendations in the
18 *Federal Register*;

19 “(C) provide for a period of 30 days for the
20 public to provide written comments on such rec-
21 ommendations;

22 “(D) hold a meeting at which the public
23 may present its views on such recommendations;
24 and

1 “(E) after consideration of such public
2 views and comments, revise such recommenda-
3 tions as necessary.

4 “(5) *TRANSMITTAL OF RECOMMENDATIONS.*—Not
5 later than January 15, 2013, the Secretary shall
6 transmit to Congress the revised recommendations
7 under paragraph (4), a summary of the views and
8 comments received under such paragraph, and any
9 changes made to the recommendations in response to
10 such views and comments.

11 “(6) *MINUTES OF NEGOTIATION MEETINGS.*—

12 “(A) *PUBLIC AVAILABILITY.*—Before pre-
13 senting the recommendations developed under
14 paragraphs (1) through (5) to Congress, the Sec-
15 retary shall make publicly available, on the
16 Internet Web site of the Food and Drug Admin-
17 istration, minutes of all negotiation meetings
18 conducted under this subsection between the Food
19 and Drug Administration and the regulated in-
20 dustry.

21 “(B) *CONTENT.*—The minutes described
22 under subparagraph (A) shall summarize any
23 substantive proposal made by any party to the
24 negotiations as well as significant controversies

1 *or differences of opinion during the negotiations*
2 *and their resolution.”.*

3 **SEC. 5. SUNSET DATES.**

4 *(a) AUTHORIZATION.—The amendments made by sec-*
5 *tion 3 shall cease to be effective October 1, 2013.*

6 *(b) REPORTING REQUIREMENTS.—The amendment*
7 *made by section 4 shall cease to be effective January 31,*
8 *2014.*

Union Calendar No. 521

110TH CONGRESS
2^D Session

H. R. 6433

[Report No. 110-805]

A BILL

To amend the Federal Food, Drug, and Cosmetic
Act to establish a program of fees relating to ge-
neric new animal drugs.

JULY 30, 2008

Reported with an amendment, committed to the Com-
mittee of the Whole House on the State of the Union,
and ordered to be printed